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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/001,737 | 12/31/1997 | LEE MIZZEN | 870109.408 | 7028 |

26161 7590 06/06/2003
FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT
1645

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|-------------------------------|-------------------------------|
| Application No. 09/001,737 | Applicant(s) Mizzen et al. |
| Examiner S. Devi, Ph.D. | Art Unit 1645 |



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Mar 19, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-39 is/are pending in the application.

4a) Of the above, claim(s) 1, 9-18, 25-30, 32, 34, and 36 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2-8, 19-24, 31, 33, 35 and 37-39 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

DETAILED ACTION

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 07/09/02 (paper no. 16) has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 07/09/02 (paper no. 18) in response to the final Office Action mailed 01/02/02 (paper no. 15).

Status of Claims

3) Claims 3-8 and 20 have been amended via the amendment filed 07/09/02.
New claims 32-39 have been added via the amendment filed 07/09/02.
Claims 1-39 are pending.
Claims 1, 9-18, 25-30, 32, 34 and 36 have been withdrawn have from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.
Claims 2-8, 19-24, 31, 33, 35 and 37-39 are pending and are under examination.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Drawings

6) The drawings are objected to under 37 C.F.R 1.84 because of the reasons set forth by the Draftsperson in the attached Form PTO 948 (paper no. 23). Correction is required. Applicants are asked to note the changes effected 03 May 2001, particularly the changes to the 'Timing of Corrections':

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85; 1097 O.G. 36

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 C.F.R 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, Applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible. Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

Specification - Informalities

7) The instant specification is objected to for the following reasons:

(a) The use of the trademarks in the instant specification has been noted in this application. For example, see page 45, last paragraph and page 48, first full paragraph: "Tween 20"; page 46, line 11 and page 43, line 22: "Triton X-100"; and page 43, line 18: "Sepharose". Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

(b) The address of the depository, ATCC, in line 13 on page 25 is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendment to the specification is suggested to reflect this. It is suggested that Applicants examine the whole specification to make similar correction to the address, wherever it appears.

Rejection(s) Withdrawn

8) The rejection of claims 4, 9-24 and 31 maintained by the previous Examiner of record in paragraph 3 of the Office Action mailed 01/02/02 (paper no. 15) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn.

9) The rejection of claim 5 maintained by the previous Examiner of record in paragraph 2 of the Office Action mailed 01/02/02 (paper no. 15) under 35 U.S.C. § 112, first paragraph, as not having possession of the claimed invention, is withdrawn.

10) The rejection of claims 2, 9-10, 19-24 and 31 maintained by the previous Examiner of record in paragraph 5 of the Office Action mailed 01/02/02 (paper no. 15) under 35 U.S.C. § 103(a) as being unpatentable over Srivastava *et al.* (WO 95/254923) in view of Hamel *et al.* (WO 96/40928) and Suzue *et al.* (*In: Stress-inducible Cellular Responses*. Freige *et al.* (Eds), pages 449-463, 1996), is withdrawn.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

11) Claims 2-8, 19-24, 31, 33, 35 and 37-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 2 is vague in the use of the abbreviated recitation "Hsp60". It is suggested that

the abbreviation be recited as a full terminology at first occurrence, with its abbreviated recitation retained in parentheses.

(b) Claims 4 and 5 are vague and confusing in the recitation "complement SEQ ID NO: 7 ...". It is unclear what is encompassed in this limitation, and how SEQ ID NO: 7 differs from "complement SEQ ID NO: 7".

(c) Claim 6 is vague in the recitation "polypeptide comprising a sequence" without distinctly reciting that the sequence is an amino acid sequence. For clarity and for distinctly claiming the subject matter, it is suggested that Applicants replace the recitation with --polypeptide comprising an amino acid sequence--.

(d) Claim 3 is vague in the recitation "nucleic acid molecule comprising the sequence of SEQ ID NO: 7" (see part b). For clarity and in order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation with --nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:--.

(e) Claim 35 is vague in the recitation "polypeptide comprises SEQ ID NO: 8" without distinctly reciting that the sequence is an amino acid sequence. For clarity and for distinctly claiming the subject matter, it is suggested that Applicants replace the recitation with --polypeptide comprises the amino acid sequence of SEQ ID NO: 8--.

(f) Claim 33 is vague in the recitation "nucleotides 15-1652 of SEQ ID NO: 7". For clarity and in order to distinctly claim the subject matter of the instant invention, it is suggested that Applicants replace the recitation with --"nucleotides 15-1652 of the nucleotide sequence of SEQ ID NO:7--.

(g) Similar criticism applies to claims 8 and claims 37-39.

(h) In claims 19 and 31, for proper antecedence, it is suggested that Applicants replace the recitation "an isolated nucleic acid molecule according to any one of claims 2-8" with --the isolated nucleic acid molecule according to any one of claims 2-8--.

(i) In claim 23, for proper antecedence, it is suggested that Applicants replace the recitation "a vector according to claim 19" with --the vector according to claim 19--.

(j) Claim 24 improperly depends from itself.

(k) Claims 7 and 20-22, which depend directly or indirectly from one of claims 2-8 or 19,

are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

12) Claims 5, 6, 19-24, 31, 38 and 39 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

It is noted that the claimed nucleic acid molecule does not exist independent of its function in encoding the Hsp60 polypeptide of *S. pyogenes*. The specification discloses diagnostic and vaccine intentions or applications. However, the instant specification fails to teach a single variant of a polypeptide sequence of SEQ ID NO: 8 that is encoded by a nucleotide sequence from *S. pyogenes* wherein the polypeptide is at least 95%, 97% or 98% homologous to SEQ ID NO: 8, or a nucleotide sequence variant comprising at least 25% of contiguous nucleotide bases of SEQ ID NO: 7 from nucleotides 15-1652 or a complement thereto, as claimed. Diagnostic applications minimally require antigen-antibody interaction, which instant claims do not require. The precise structure or relevant identifying characteristics of each DNA molecule that encodes a variant polypeptide or peptide, or a complement as claimed, wherein the polypeptide or peptide variant has the functional properties of the native Hsp60 polypeptide of *S. pyogenes*, can only be determined empirically by actually making every DNA molecule that encodes the polypeptide or peptide of the recited variability, i.e., the instantly recited at least 95%, 97% or 98% sequence identity, and testing each varied DNA molecule or a complement thereof to determine whether it encodes a polypeptide or peptide variant having the particularly disclosed functional properties of the native Hsp60 polypeptide of *S. pyogenes*. The

Written Description Guidelines state:

There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

The description provided for SEQ ID NO: 7 and 8 is insufficient description for the various claimed variant species. The Hsp60 polypeptide of *S. pyogenes* has specific biological properties dictated by the structure of the polypeptide and the corresponding structure of the structural gene sequence which encodes it. There has to be some nexus between the structure of the gene sequence, the

structure of the polypeptide encoded, and the function of the encoded polypeptide. However, the function cannot be predicted from the modification of the structure of the gene and in the instant case, the DNA encoding the polypeptide variant. Applicants have not shown that modification of a reference nucleotide sequence encoding a reference polypeptide variant as claimed would automatically predict the production of a Hsp60 polypeptide variant of *S. pyogenes* as disclosed. The specification fails to describe the structure or relevant identifying characteristics of a representative number of DNA species encoding a representative number of species of *S. pyogenes* Hsp60 polypeptide variants of at least 95%, 97% or 98% sequence identity as claimed, sufficient to allow one skilled in the art to determine that the inventors had possession of the invention as claimed. With the exception of an isolated polynucleotide of the nucleotide sequence, SEQ ID NO: 7, encoding the polypeptide of SEQ ID NO: 8, a skilled artisan cannot envision the detailed chemical structure of all the variant nucleotide sequences encompassed by the DNA molecules. Regardless of the complexity or simplicity of the method of isolation, conception cannot be achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is a part of the invention and a reference to a potential method of isolating it. The nucleic acid variant itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. See Written Description Requirement, *Federal Register*, vol. 66, no. 4, Notices, pp. 1099-1111, 05 January 2001).

Rejection(s) under 35 U.S.C. § 102

13) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

14) Claims 4, 19-24 and 31 are rejected under 35 U.S.C § 102(e) as being anticipated by Covacci *et al.* (US 6,077,706).

Covacci *et al.* taught an isolated nucleic acid comprising at least 24 contiguous nucleotides and showing 100% sequence homology with a fragment of the instantly recited SEQ ID NO: 7 from nucleotides 15-1652 (see the attached search report). That this nucleic acid molecule hybridizes to SEQ ID NO: 7 in the region from nucleotides 15-1652 under the recited hybridization conditions, or comprises a complement thereto, is inherent from the teachings of Covacci *et al.* The polynucleotide is taught to be double- or single-stranded (see paragraph bridging columns 5 and 6). An expression vector comprising the nucleic acid molecule and a promoter operably linked to the nucleic acid molecule, and mammalian host cells containing the vector are taught (see columns 8, 9 and 13). The nucleic acid molecule is present in water, i.e., a diluent (see lines 60 and 61 in column 25).

Claims 4, 19-24 and 31 are anticipated by Covacci *et al.*

15) Claim 2 is rejected under 35 U.S.C § 102(b) as being anticipated by Hamel *et al.* (WO 96/40928, already of record).

It is noted that the instant claim does not structurally define Hsp60 or the nucleic acid molecule encoding the same.

Hamel *et al.* disclosed a nucleotide sequence derived from *Streptococcus pyogenes* that encodes a heat shock protein (see abstract; page 75-77; and claims). The prior art nucleotide sequence derived from *Streptococcus pyogenes* encoding a heat shock protein is viewed as the same as the Applicants' claimed product, which is identified by Applicants with a different name, i.e., Hsp60.

Claim 2 is anticipated by Hamel *et al.*

16) Claims 8, 19-24 and 37 are rejected under 35 U.S.C § 102(b) as being anticipated by Labigne *et al.* (WO 94/26901).

Labigne *et al.* taught an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an at least 8 contiguous amino acid-long peptide that has 100% sequence identity with an at least 8 contiguous amino acid-long peptide of a streptococcal Hsp60 having the amino acid sequence in the region of 1-545 residues of SEQ ID NO: 8 (see the attached search report). An expression vector comprising the nucleic acid molecule and prokaryotic or eukaryotic host cells transformed by the expression vector are taught (see claims 10-16, 2-26; Figures and Sequence Listing). In spite of the fact that Labigne *et al.* do not expressly teach the

functional limitation recited by Applicants, since the prior art peptide encoded by the prior art nucleic acid molecule is structurally the same as the instantly recited peptide, the peptide is expected inherently to bind to a major histocompatibility complex molecule. The Office's position that Labigne's nucleic acid molecule and the peptide encoded by the same are the same as the Applicants' nucleic acid molecule and the encoded peptide is based upon the fact that every characteristic overlapping in Labigne's and Applicants' disclosure are the same.

Claims 8, 19-24 and 37 are anticipated by Labigne *et al.*

Objection(s)

17) Claims 3-8, 20, 33, 35 and 37-39 are objected to for the following reasons:

- (a) Claims 3-8, 20, 33, 35 and 37-39 are objected for including non-elected subject matter.
- (b) Claim 20 is objected to for missing a period at the end of the claim.

Remarks

18) Claims 2-8, 19-24, 31, 33, 35 and 37-39 stand rejected.

19) Papers related to this application may be submitted to Group 1600, AU 1641 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

20) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

May, 2003

SD
S. DEVI, PH.D.
PRIMARY EXAMINER

SEO ID 8

RESULT 14
 AAR67383
 ID AAR67383 standard; Protein; 544 AA.
 XX
 AC AAR67383;
 XX
 DT 22-JUN-1995 (first entry)
 XX
 DE C. psittaci HypB gene product.
 XX
 KW Urease; immunogen; vaccine; diagnostic; heat shock protein; HSP;
 KW GroEL-like protein; Helicobacter felis.
 XX
 OS Chlamydia psittaci.
 XX
 PN WO9426901-A.
 XX
 PD 24-NOV-1994.
 XX
 PF 19-MAY-1994; 94WO-EP01625.
 XX
 PR 19-MAY-1993; 93EP-0401309.
 PR 19-NOV-1993; 93WO-EP03259.
 XX
 PA (INRM) INST NAT SANTE & RECH MEDICALE.
 PA (INSP) INST PASTEUR.
 XX
 PI Ferrero R, Labigne A, Suerbaum S, Thibierge J;
 XX
 DR WPI; 1995-006797/01.
 XX
 PT DNA from Helicobacter pylori and Helicobacter felis - used to
 develop prods. for detection, treatment and prevention of
 PT Helicobacter infection
 XX
 PS Disclosure; Fig. 7A(i-vii); 168pp; English.
 XX
 CC The sequence of the Helicobacter pylori heat shock protein A
 CC (given in AAR67374) was compared to that of other GroEL-like
 CC proteins from Legionella pneumophila (AAR67381), Escherichia coli
 CC (AAR67382), Chlamydia psittaci (AAR67383), Mycobacterium leprae
 CC (AAR67384) and human mitochondrial protein P1 (AAR67385), and regions
 CC of homology were identified.
 XX
 SQ Sequence 544 AA;
 Query Match 4.4%; Score 24; DB 16; Length 544;
 Best Local Similarity 100.0%; Pred. No. 3.7e-14;
 Matches 24; Conservative 0; Mismatches 0; Indels 0; Gaps 0
 Qy 273 AVKAPGFGDRRKAMLEDIAILTGG 296
 |||||||
 Db 275 AVKAPGFGDRRKAMLEDIAILTGG 298

RESULT 6
US-08-470-260-7
; Sequence 7, Application US/08470260
; Patent No. 6077706
; GENERAL INFORMATION:
; APPLICANT: Covacci, Antonello
; APPLICANT: Bognoli, Massimo
; APPLICANT: Telford, John
; APPLICANT: Macchia, Giovanni
; APPLICANT: Rappuoli, Rino
TITLE OF INVENTION: Helicobacter Pylori Proteins Useful
TITLE OF INVENTION: for Vaccines and Diagnostics
NUMBER OF SEQUENCES: 7
CORRESPONDENCE ADDRESS:
; ADDRESSEE: Chiron Corporation
; STREET: 4560 Horton Street
; CITY: Emeryville
; STATE: California
; COUNTRY: USA
; ZIP: 94608-2916
COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/470,260
; FILING DATE:
; CLASSIFICATION:
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: US 08/256,848
; FILING DATE: 21-OCT-1994
; ATTORNEY/AGENT INFORMATION:
; NAME: McClung, Barbara G.
; REGISTRATION NUMBER: 33,113
; REFERENCE/DOCKET NUMBER: 0316.001
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: (510) 601-2708
; TELEFAX: (510) 655-3542
; INFORMATION FOR SEQ ID NO: 7:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 1838 base pairs
; TYPE: nucleic acid

SEQ ID NO: 7

